REMARKS

Claims 1-31, 33-90 and 93-124 were pending and claims 30, 31, 33-35, and 90 were under consideration in the application. Claims 1-29, 36-89 and 93-124, withdrawn from consideration as directed to non-elected inventions, have been canceled without prejudice. Claim 31 has been amended to clarify the claim language.

No new matter has been added.

Rejection under 35 U.S.C. § 101

Claims 30, 31, 33-35 and 90 remain rejected under 35 U.S.C. § 101 because the claims are allegedly "drawn to an invention with no apparent or disclosed specific and substantial credible utility ..." (Office Action, page 2). The Office alleges that the "instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder of [sic] physiological process which one would wish to manipulate for a desired clinical effect." The Office indicated that arguments presented by Applicants in response to the previous Office Action, although considered, were not deemed persuasive. Applicants respectfully disagree.

The specification recites that the claimed receptor is a GPCR and is useful, *inter alia*, in the treatment and diagnosis of schizophrenia and other mental diseases/disorders. The specification also recites that the claimed polypeptides are useful in the diagnosis and/or treatment of hypotension. As set forth below, the claimed receptor is a rhodopsin GPCR. Rhodopsin GPCRs are known to bind to ligands including amines, peptides and large proteins. A BLAST alignment of the nucleic acid molecule encoding the presently claimed polypeptide reveals 100% homology to known human leukocyte platelet-activating factor receptors (also known as platelet activating factor receptor or PAF receptor) (*see* attached BLAST alignment (pages 21 of 43, for example) and Sequence Viewers).

The leukocyte platelet-activating factor receptor is in the rhodopsin family of GPCRs. The roles of rhodopsin GPCRs are well-known to the art-skilled. Leukocyte platelet-activating factor receptors play several roles including granulocyte activation and

chemotaxis, platelet activation, enhancement of vascular permeability, smooth muscle contraction, bronchospasm, and hypotension. (*See*, Kunz *et al.*, J. Biol. Chem., 267, 13:9101-9106; hereinafter "Kunz"; copy attached hereto). As discussed in greater detail below, the significant homology between the claimed polypeptides and leukocyte platelet-activating factor receptors supports the assignment of the utilities of the leukocyte platelet-activating factor receptor to the presently claimed polypeptides. Therefore, specific, substantial and credible utilities exist for the claimed receptors.

Utility Examination Guidelines

The Utility Examination Guidelines (the "Guidelines") require that a claimed invention have a specific, substantial and credible asserted utility, or, alternatively a well-established utility. Applicants have asserted that the claimed polypeptides are useful, *inter alia*, to generate antibodies specific for the claimed polypeptides. As discussed in greater detail below, the claimed polypeptides share 100% sequence homology with known leukocyte platelet-activating factor receptors. The fact that the claimed polypeptides share such homology with receptors with a known function supports the assignment of the same specific, substantial, and credible utilities of the known receptors to the claimed polypeptides. The utilities asserted are art-established: those skilled in the art would readily acknowledge that the claimed polypeptides are useful within the meaning of 35 U.S.C. § 101.

As Applicants have asserted utilities that are specific, substantial and credible, and well established, the Utility Requirement has been satisfied. Applicants therefore respectfully request the withdrawal of the rejection under 35 U.S.C. § 101.

Under the Guidelines, Office personnel are instructed to review the specification and claims of the application to determine if a specific and substantial utility that is credible is present. The Guidelines note that the specific and substantial requirement "excludes 'throw-away', insubstantial,' or 'nonspecific' utilities, such as the use of a complex invention as landfill." The Guidelines go on to note that an Examiner's "*prima*

facie showing ***must*** establish that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial." "If the applicant has asserted that the claimed invention is useful for any particular practical purpose (*i.e.*, it has a 'specific and substantial utility') and the assertion would be considered credible by a person of ordinary skill in the art, do ***not*** impose a rejection based on lack of utility." (Guidelines, emphasis added).

The Guidelines comment on the use of computer based analysis of nucleic acids to assign functions to a nucleic acid or polypeptide based upon homology to sequences found in databases. Specifically, the Guidelines state that the:

> suggestions to adopt a *per se* rule rejecting homology based assertions of utility ***are not adopted.*** An applicant is entitled to a patent to the subject matter claimed unless statutory requirements are not met (35 U.S.C. 101, 102, 103, 112) . . .The inquiries involved in assessing utility are fact dependent, and the determinations must be made on the basis of scientific evidence. Reliance on the commenters' *per se* rule, rather than a fact dependent inquiry, is impermissible because the commenters provide no scientific evidence that homology-based assertions of utility are inherently unbelievable or involve implausible scientific principles. *See, e.g., In re Brana,* 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (rejection of claims improper where claims did 'not suggest an inherently unbelievable undertaking or involve implausible scientific principles' and where ''prior art * * * discloses structurally similar compounds to those claimed by the applicants which have been proven * * * to be effective').
>
> A patent examiner ***must*** accept a utility asserted by an applicant unless the Office has evidence or sound scientific reasoning to rebut the assertion. The examiner's decision must be supported by a preponderance of all the evidence of record. *In re Oetiker,* 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). More specifically, when a patent application claiming a nucleic acid asserts a specific, substantial, and credible utility, and bases the assertion upon homology to existing nucleic acids or proteins having an accepted utility, the asserted utility must be accepted by the examiner unless the Office has sufficient evidence or sound scientific reasoning to rebut such an assertion. ''[A] 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient.'' *Fujikawa* v. *Wattanasin,* 93 F.3d 1559, 1565, 39 USPQ2d 1895, 1900 (Fed. Cir. 1996). The Office will take into account both the nature and degree of the homology.
>
> When a class of proteins is defined such that the members share a specific, substantial, and credible utility, the reasonable assignment of a new protein to the class of sufficiently conserved proteins would impute the same

> specific, substantial, and credible utility to the assigned protein. If the preponderance of the evidence of record, or of sound scientific reasoning, casts doubt upon such an asserted utility, the examiner should reject the claim for lack of utility under 35 U.S.C. 101. For example, where a class of proteins is defined by common structural features, but evidence shows that the members of the class do not share a specific, substantial functional attribute or utility, despite having structural features in common, membership in the class may not impute a specific, substantial, and credible utility to a new member of the class. When there is a reason to doubt the functional protein assignment, the utility examination may turn to whether or not the asserted protein encoded by a claimed nucleic acid has a well-established use. If there is a well-established utility for the protein and the claimed nucleic acid, the claim would meet the requirements for utility under 35 U.S.C. 101. If not, the burden shifts to the applicant to provide evidence supporting a well-established utility. There is no *per se* rule regarding homology, and each application must be judged on its own merits.

(Guidelines; emphasis added).

Preliminarily, Applicants remind the Office that specific and substantial utilities have been provided for the claimed polypeptides and that the asserted utilities are credible to one of skill in the art. The Office has failed to provide any evidence that "it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial."

Art-Recognized Utility

The Utility requirement may also be satisfied by an "Art Established Utility" which means that "a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention... and the utility is specific, substantial and credible." (M.P.E.P. §2107).

The claimed polypeptides are supported by an art-recognized utility. The art skilled would readily agree that the PAF receptor has a known utility. The present application also recites that the present invention is useful, *inter alia*, in the diagnosis and treatment for diseases or disorders such as hypotension (*see*, for example, paragraph [00141]).

Applicants also note that the biotechnology industry provides further proof that utilities for polypeptides similar to the claimed polypeptides are well established. Preliminarily, Applicants note that a monoclonal antibody against PAF receptor is commercially available *(see* attached Cayman Chemicals Product Sheet). Applicants remind the Office that the nucleic acid encoding the claimed polypeptides shares 100% sequence homology with the human leukocyte platelet-activating factor receptor (PAF receptor).

Applicants also point out that commercial products relating to GPCRs for which no ***confirmed*** function has been identified are readily available. GPCRs, ORF clones of GPCRs, and antibodies that bind to GPCRs are commercially available. For example, Applicants points out that FabGennix Inc. of Shreveport, Louisiana sells an antibody directed to Retinal Anti-GP75. GPCR75 is said to be a GPCR for which a ligand has not yet been identified. (*see* attached product sheet). Invitrogen sells ORF clones of GPCRs including those for which a ligand has not yet been identified (*see* attached list, especially noting Clone Ids IOH22483, IOH14039, IOH13056, IOH22637, IOH13239, and IOH13516). MD Bio of Taiwan sells GPCR peptides and antibodies against such peptides, again where no ligand has yet been identified.

The fact that companies make and sell such products proves that there is a well-established utility for the presently claimed polypeptides. Accordingly there could be no better proof of the utilities of the claimed polypeptides- such products are made by a manufacturer (who expects to sell them) for consumers (who expect to buy them). Any argument that there is no art-recognized utility for such polypeptides seems to place the Patent Office in direct conflict with the established practices of industry.

Specific Utility

The Utility Examination Guidelines also require a claimed invention to have a utility that is specific to the subject matter claimed (a "specific utility"). As acknowledged by the Office, the presently claimed invention can be used for many different purposes. The present application recites, for example, that the claimed

invention can be used, *inter alia*, to generate antibodies specific for the claimed polypeptides or as GPCRs. As discussed, at least one antibody directed to the leukocyte platelet-activating factor receptor (PAF receptor) is presently commercially available. Thus, there is no question that Applicants have asserted at least one specific utility and, in fact, have provided numerous specific utilities for the polypeptides of the present invention.

The Training Materials associated with the Utility Examination guidelines address the issue of specificity with reference to two kinds of asserted utilities: "specific" utilities which meet the statutory requirements, and "general" utilities which do not. The Training Materials define a "specific utility" as follows:

> A [specific utility] is *specific* to the subject matter claimed. This contrasts to *general* utility that would be applicable to the broad class of invention. For example, a claim to a polynucleotide whose use is disclosed simply as "gene probe" or "chromosome marker" would not be considered to be specific in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

The Training Materials further distinguish between "specific" and "general" utilities by assessing whether the asserted utility is sufficiently "particular," or unique (Training Materials at p.52) as compared to the "broad class of invention." Applicants note that such "unique" or "particular" utilities never have been required by the law.

To meet the utility requirement, the invention must be "practically useful," *Anderson v Natta*, 480 F.2d 1392, 1397 (CCPA 1973) and confer a "specific benefit" on the public. *Brenner v. Manson*, 383 U.S. 519, 534 (1966). The threshold of utility under this standard is not high, and requires merely an "identifiable" benefit. *Juicy Whip Inc. v. Orange Bang Inc.*, 51 USPQ2d 1700 (Fed. Cir. 1999). In *Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180 (Fed. Cir. 1991), the CAFC explained that "An invention need not be the best or only way to accomplish a certain result, and it need only be useful to some extent and in certain applications: "[T]he fact that an invention has only limited utility and is

only operable in certain applications is not grounds for finding lack of utility." *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 762, 221 USPQ 473, 480 (Fed. Cir. 1984).

This does not preclude a general utility. Practical real-world uses are ***not*** limited to uses that are unique to a single invention. The law requires that the practical utility be "definite," not particular to only one invention. *Standard Oil Co. v. Montedison,* 664 F.2d 356, 375 (3d Cir. 1981). The courts have not rejected an assertion of utility on the grounds that it is not "particular" or "unique" to the specific invention; where courts have found utility to be too "general," it has been in situations when the asserted utility in the patent disclosure was not a practical use that conferred a specific benefit. That is, a person of ordinary skill in the art would have been left to guess as to how to benefit at all from the invention. In *Kirk*, for example, the CCPA held the assertion that a man-made steroid had "useful biological activity" was insufficient where there was no information in the specification as to how that biological activity could be practically used. *Kirk*, 376 F.2d at 941.

Inventions that achieve a practical use, a use that is also achieved by other inventions, satisfy the utility requirement. Thus practical utilities can be directed to classes of inventions, so long as a person of ordinary skill in the art would understand how to achieve a practical benefit from knowledge of the class. *Montedison*, 664 F.2d at 374-75. For example, many materials conduct electricity. This general utility applies to a broad class of inventions (conductive materials) and satisfies the utility requirement of section 101. The fact that other materials also conduct electricity does ***not*** mean that other materials that conduct electricity want for utility. What is important, however, is that GPCRs are known to have practical uses. GPCRs, for example, all have practical uses well beyond throwaway uses like snake food. All of the genes encoding GPCRs can be used, for example, for toxicology testing to generate information useful in activities such as drug development, even in cases where little is known as to how a particular GPCR works. No additional experimentation would be required, therefore, to determine whether a GPCR has a practical use because all GPCRs have at least one practical use.

The Office appears to be under the impression that inventions that are, *inter alia*, useful for use in research are unpatentable. This is not true. The Patent Office's patent database is replete with patents claiming useful research tools, *e.g.*, spectrophotometers. A material whose only use is as a tool in research may indeed be patentable. *Brenner* and *Kirk* exclude only those research purposes where the ***only*** use of the material itself is as the subject of research. If *Brenner* and *Kirk* had held otherwise, any chemical material would, by virtue of its existence, be useful. However, nowhere do those cases state or imply that a material cannot be patentable if has some other beneficial use in research.

Assay methods, like many other tools used in research, have an immediately realizable "real world" value. For example, an assay method that can identify chemical compounds that possess a particular physical, structural or biological property clearly have "real world" value irrespective and independent from the utility that may be associated with the compounds identified using the assay method. As a consequence, a presumption that assay methods cannot possess utility if the compound isolated or identified using the assay do not have utility would be the product of a flawed analysis of *Brenner*. Such a conclusion also would suggest that processes and products can never possess utility if their utility lies in the field of research. Indeed, the application of this concept of the utility requirement as it relates to methods for assaying or identifying compounds, if taken literally, would mean that claims to methods such as NMR, infrared, x-ray crystallography, and screening for other important biological properties, would be unpatentable because further research would be necessary to establish utility for the compounds identified or assayed. This certainly cannot be the result intended by the Patent Office when issuing these guidelines.

Because all GPCRs, as a class, convey practical benefit (much like the class of DNA ligases identified in the Training Materials), there should be no need to provide additional information about them. A person of ordinary skill in the art need not guess whether any given GPCR conveys a practical benefit. Nor is it necessary to know how or why any given GPCR works. It is settled law that how or why any invention works is irrelevant to determining utility under 35 U.S.C. § 101: "[I]t is not a requirement of

patentability that an inventor correctly set forth, or even know, how or why the invention works." *In re Cortwright*, 165 F.3d 1353, 1359 (Fed. Cir. 1999) (quoting *Newman v. Quigg*, 877 F.2d 1575, 1581 (Fed. Cir. 1989).

Applicants need only prove a "substantial likelihood" of utility; certainty is not required. *Brenner*, 383 U.S. at 532. The amount of evidence required to prove utility depends on the facts of each particular case. *In re Jolles*, 628 F.2d 1322, 1326 (CCPA 1980). "The character and amount of evidence may vary, depending on whether the alleged utility appears to accord with or to contravene established scientific principles and beliefs." *Id.* Unless there is proof of "total incapacity," or there is a "complete absence of data" to support the applicant's assertion of utility, the utility requirement is met. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992); *Envirotech*, 730 F.2d at 762. The Office has failed to provide proof of "total incapacity", and Applicants have provided information that supports the asserted utilities.

Substantial Utility

In addition to conferring a specific benefit on the public, the benefit must also be "substantial". *Brenner*, 383 U.S. at 534. A "substantial" utility is a practical, "real world" utility. *Nelson v. Bowler*, 626 F.2d 853, 856 (CCPA 1980). An asserted utility for a compound that merely invites further research to determine a practical utility is not substantial. In *Brenner*, for example, the U.S. Supreme Court held that a process for making a compound does not confer substantial benefit where the only known use of the compound was to be the object of further research. *Id.* at 535. Similarly, in *In re Kirk*, the CCPA held that compound would not confer substantial benefit on the public merely because it might be used to synthesize some other, unknown compound that would confer substantial benefit. *Kirk*, 376 F.2d at 945.

Applicants teach, as described above, that the claimed invention can be used for the production of antibodies. As leukocyte platelet-activating factor receptors (PAF receptors) have established biological roles and are known to be involved in, *inter alia*, hypotension, the claimed polypeptides also have a substantial utility and, thus, it is clear

that the claimed invention has real-world uses. All the uses described in the present application are real-world uses and, again, stand in stark contrast to the "throw away" uses (*e.g.*, landfill component or snake food) set forth in the utility guidelines. Thus, there is no question that Applicants have asserted at least one substantial utility and, in fact, have provided numerous substantial utilities. Accordingly, Applicants have complied with the substantial utility requirement.

The Office appears to be under the impression that inventions that are, *inter alia*, useful for use in research are unpatentable. This is not true. The Patent Office's patent database is replete with patents claiming useful research tools, *e.g.*, spectrophotometers. A material whose only use is as a tool in research may indeed be patentable. *Brenner* and *Kirk* exclude only those research purposes where the ***only*** use of the material itself is as the subject of research. If *Brenner* and *Kirk* had held otherwise, any chemical material would, by virtue of its existence, be useful. However, nowhere do those cases state or imply that a material cannot be patentable if has some other beneficial use in research.

Assay methods, like many other tools used in research, have an immediately realizable "real world" value. For example, an assay method that can identify chemical compounds that possess a particular physical, structural or biological property clearly have "real world" value irrespective and independent from the utility that may be associated with the compounds identified using the assay method. As a consequence, a presumption that assay methods cannot possess utility if the compound isolated or identified using the assay do not have utility would be the product of a flawed analysis of *Brenner*. Such a conclusion also would suggest that processes and products can never possess utility if their utility lies in the field of research. Indeed, the application of this concept of the utility requirement as it relates to methods for assaying or identifying compounds, if taken literally, would mean that claims to methods such as NMR, infrared, x-ray crystallography, and screening for other important biological properties, would be unpatentable because further research would be necessary to establish utility for the compounds identified or assayed. This certainly cannot be the result intended by the Patent Office when issuing these guidelines.

The claimed invention in *Brenner* was directed to a method whose ***only*** utility was making a class of steroids. The disclosure in Brenner failed to disclose a utility for the products of that method, which in turn led to a § 101 rejection because the products resulting from the method lacked utility. The Applicant in Brenner admitted that the products produced by the method would not be patentable if they lacked utility. 148 USPQ 696. The Court stated that the method lacked utility as well, holding:

> We find absolutely no warrant for the proposition that although Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing, a different set of rules was meant to apply to the process which yielded the unpatentable product.

148 USPQ 696.

In *Brenner*, the method of making the compounds, which was the only use recited, was inextricably bound up with the compounds themselves and, as a result, the requirement for utility could not be met until a use for the compounds was found. The Court emphasized that the utility of the claimed invention (i.e., the products) would require further research to identify and ascertain, and the compounds produced by the method would be the objects of that research.

In contrast, GPCRs ***identical*** to known receptors having known functions stand on a very different basis. As discussed, there are a multitude of utilities for the claimed polypeptides, including, but not limited to, their ability to facilitate research.

The Claimed Invention Has A Credible Utility

In addition to a specific and substantial utility, the Utility Examination Guidelines require that such utility be "credible" (a "credible utility"). That is, whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided. The asserted utilities are credible. Clearly, the claimed polypeptides are not asserted to be a universal cure for cancer or represent a treatment for baldness. Again, as discussed, the fact that the claimed polypeptides share 100% sequence identity with a leukocyte platelet-activating factor receptor (PAF receptor) supports the assignment of the same specific, substantial, and credible utility shared by

leukocyte platelet-activating factor receptors to the claimed polypeptides. The Office has failed to provide any evidence or scientific reasoning, less still a preponderance of evidence casting doubt upon such an asserted utility. Further, the Office has not provided any evidence that leukocyte platelet-activating factor receptors do not possess a specific, substantial functional attribute or utility.

The Office has failed to provide any "countervailing evidence" required by the Utility Examination Guidelines to show that the relationship does not exist. Therefore, no countervailing evidence that says the present invention does not have a substantial, credible, and useful invention has been provided.

Applicants further assert that long held pre-Brenner case law standard supports judging the utility of an invention on whether or not the public derives a benefit from the invention, regardless of how slight the benefit. *See,* for example, *In re Nelson*, 280 F.2d 172, 178-180 (C.C.P.A. 1960) (stating that "however slight the advantage which the public have received from the inventor, it offers a sufficient reason for his compensation") (citing ROBINSON ON PATENTS (1890)); *see also Lowell v. Lewis*, 1 Mason 182 (Fed. Case. No. 8568, 1817) (stating "if it be more or less useful is... of no importance to the public. If it be not extensively useful it will silently sink into contempt and disregard"). Polypeptides of all types are broadly used in the biotechnology industry, playing key roles in drug and disease discovery processes. Indeed, many such fragments enable researchers to find the genes associated with physiological functions. The discovery of such functions readily benefits the public. Accordingly, such tools should satisfy the pre-Brenner case law standard.

Applicants have demonstrated a "substantial likelihood" of utility by showing a "reasonable correlation" between the utility of the known compositions (PAF receptors) and the composition being claimed. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1565 (Fed. Cir. 1996). Indeed, the fact that the nucleic acid sequence encoding the claimed polypeptides shares 100% sequence identity with a known PAF receptor indicates that the more than a "reasonable correlation" has been provided. The Office has neither provided

evidence nor sound scientific reasoning that one skilled in the art would doubt the "reasonable correlation" advanced by Applicants. Accordingly, under *Brana*, the Patent Office ***must*** accept the utility asserted by Applicants.

Summary of 35 U.S.C. § 101 Issues

The Utility Examination Guidelines note that an Examiner's "*prima facie* showing ***must*** establish that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial." "If the applicant has asserted that the claimed invention is useful for any particular practical purpose (*i.e.*, it has a 'specific and substantial utility') and the assertion would be considered credible by a person of ordinary skill in the art, do ***not*** impose a rejection based on lack of utility." Applicants have asserted that the claimed polypeptides are useful, *inter* alia, to generate antibodies specific for the claimed polypeptides. As discussed the nucleotides encoding the claimed polypeptides share 100% sequence homology with leukocyte platelet-activating factor receptors, receptors known to be involved in hypotension, a utility asserted in the application as originally filed. The fact that the claimed polypeptides share such sequence homology with known receptors supports the assignment of the same specific, substantial, and credible utilities of leukocyte platelet-activating factor receptors to the claimed polypeptides. The utilities asserted are by Applicants art-established: those skilled in the art would readily acknowledge that the claimed polypeptides are useful within the meaning of 35 U.S.C. § 101.

A patent examiner ***must*** accept a utility asserted by an applicant unless the Office has evidence or sound scientific reasoning to rebut the assertion. The Guidelines make clear that when a patent application claiming a nucleic acid, for example, asserts a specific, substantial, and credibility, and bases the assertion upon homology to existing nucleic acids or proteins having an accepted utility, the asserted utility ***must*** be accepted by the examiner unless the Office has sufficient evidence or sound scientific reasoning to rebut such an assertion. The Office has failed to provide any evidence, less still a

preponderance of the evidence, to cast doubt upon any of the asserted utilities. The Office has also failed to provide any evidence that the asserted utilities are "throwaway utilities" or that the claimed polypeptides are inappropriate or unsuited for the several asserted utilities. Finally, even assuming *arguendo* that the asserted utilities are not specific or substantial, the art established utilities for the claimed polypeptides satisfy the Utility requirement of § 101.

Applicants therefore respectfully request the withdrawal of the rejection under 35 U.S.C. § 101.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 30, 31, 33-35 and 90 remain rejected and new claims 142-144 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to adequately teach how to use the instant invention for the reasons provided with the rejection under 35 U.S.C. § 101. Applicants do not agree.

As discussed above, the present invention ***is*** supported by a specific, substantial, and credible asserted utility as well as a well-established utility. One skilled in the art having read the present application would be able to make and use the claimed invention.

Claims 33 and 90 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully disagree.

According to the Office, "one can not produce a protein comprising an epitope that is 'specific' thereto [to SEQ ID NO:67] because the instant specification does not identify those portions of SEQ ID NO:67 which Applicant believes to be 'specific' thereto and those portions believed to be shared with homologous and orthologous proteins." (Office Action, pages 5-6).

A patent need not teach, and preferably omits, what is well known in the art. *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 221 U.S.P.Q. 481, 489 (Fed. Cir. 1984). Applicants are ***not*** required to provide a specification that describes anything and everything upon which the claims could ever be construed to read. If Applicants were held to such a standard, no specification could ever be deemed to meet the written description requirement. As previously discussed, the specification adequately describes ***the subject matter defined by the present claims***, which is all that the law requires.

As set forth in paragraph [00126], "the term 'specific for,' when used to describe antibodies of the invention, indicates that the variable regions of the antibodies of the invention recognize and bind nGPCR-x polypeptides exclusively (*i.e.*, are able to distinguish nGPCR-x polypeptides from other known GPCR polypeptides by virtue of measurable differences in binding affinity, despite the possible existence of localized sequence identity, homology, or similarity between nGPCR-x and such polypeptides)."

The art skilled would readily agree that the inventors possessed the claimed invention at the time the application was filed. In order to determine which epitopes were "specific to SEQ ID NO:67", the skilled artisan need only compare the polypeptide sequence of SEQ ID NO:67 to other GPCR sequences. Such a comparison is well within the purview of the art-skilled and constitutes routine experimentation.

The subject matter encompassed by the pending claims is described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Therefore Applicants respectfully request that the rejection of the pending claims under 35 U.S.C. § 112, first paragraph, be withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 31, 34, 35 and 90 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Applicants disagree.

The proper inquiry, when determining whether a claim satisfies the requirements of 35 U.S.C. § 112, second paragraph, is a determination "whether those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics Inc. v. Safety Travel Chairs, Inc.*, 1 U.S.P.Q.2d 1081, 1088 (Fed. Cir. 1986). Thus, if those skilled in the art can understand what is claimed when the claim is read in light of the specification, a rejection under 35 U.S.C. § 112, second paragraph, is inappropriate.

Claims 31 is said to be confusing because it claims a polypeptide comprising 'a sequence of SEQ ID NO:67' because it implies that there is more than one sequence in SEQ ID NO:67." Accordingly, claim 31 has been amended to recite "the sequence of SEQ ID NO:67."

Claims 34, 35 and 90 are said to be vague in their recitation "of the term 'nGPCR-93' as a limitation." (Office Action, page 6). Applicants respectfully assert that the skilled artisan would find the claims clear and definite. For example, given the amino acid sequence of nGPCR-93, the art-skilled could readily determine which portions thereof represent extracellular domains thereof. Similarly, simply by using multiple sequence alignment tools, tools that were generally available at the time of filing of the present invention, the art-skilled could determine which epitopes were specific to nGPCR-93.

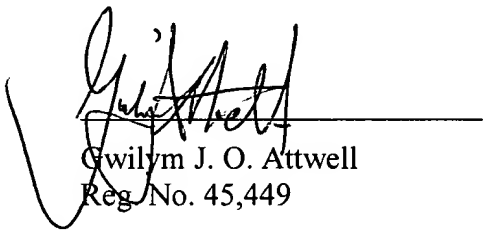
Claim 34 is further said to be " 'confusing' in so far as it recites 'said polypeptide comprises comprises [sic] at least one". (Office Action, page 6). As best understood by Applicants, the Examiner is questioning the claimed of "at least one extracellular domain." The skilled artisan would readily understand that receptors frequently comprise more the one extracellular domain. Using methodologies described above and generally known to the art-skilled, one could readily identify those domains in nGPCR-93 that are extracellular.

Because one of skill in the art would understand what is claimed when the claim is read in light of the specification, Applicants respectfully request that the rejection of the pending claims under 35 U.S.C. § 112, second paragraph, be withdrawn.

Conclusion

Applicants believe the claims are in condition for allowance. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (215) 665-6904 to clarify any unresolved issues raised by this response.

Respectfully submitted,



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Attachments: BLAST alignment
NCBI Sequence Viewers (x3)
Kunz *et al.*, J. Biol. Chem., 267, 13:9101-9106
Product Sheet for Mab against PAF receptor
Product Sheet for GPCR ORF Clones (Invitrogen)
Product Sheet for Anti-GPCR-75 Antibodies
Product sheet for GPCR control peptides and antibodies (MD Bio)

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